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EXAMINER

PATEL, MITAL B

ART UNIT PAPER NUMBER

3761

DATE MAILED: 06/18/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/616,483

Applicant(s)

HOFFMAN, ANDREW M.

Examiner

Mital B. Patel

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 3, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Barney et al (US 65100818).
4. **As to claim 1**, Barney teaches a drug delivery device for a mammal comprising a cup-shaped body **110**, said body enclosing only one external nare (**see Col. 6, lines 7-15**), wherein the device does not extend into the nostril of the mammal and the device comprises an interfacing lumen the diameter which does not enclose a second nare of the mammal (**See Figure 4A**).
5. **As to claim 3**, Barney teaches a device wherein the device does not enclose the mouth of the mammal (**See Figure 4A**).

Art Unit: 3761

6. **As to claim 6**, Barney teaches a device wherein the interfacing lumen comprises a diameter which covers only one nare and not both nares a horse, a cow, a sheep, or a goat (**See Col. 6, lines 7-15**).

7. **As to claim 7**, Barney teaches a device wherein the device is adapted for use on a horse.

8. **As to claim 8**, Barney teaches a device wherein the cup-shaped body comprises a flexible interface for contacting the face of the mammal.

9. **As to claim 9**, Barney teaches a device wherein the interface is angled.

10. **As to claim 10**, Barney teaches a device wherein the interface is straight.

11. **As to claim 11**, Barney teaches a device wherein the device comprises a spacer holding chamber, the chamber being in communication with the cup-shaped body (**See Figure 4A**).

12. **As to claim 12**, Barney teaches a device wherein the chamber comprises a lumen for receiving a therapeutic agent.

13. **As to claim 13**, Barney teaches a device wherein the lumen is adapted to receive an aerosol container.

14. **As to claim 14**, Barney teaches a device wherein the lumen is adapted to receive a metered-dose inhaler (MDI) canister.

15. **As to claim 15**, Barney teaches a method for preventing or treating a respiratory condition of a mammal, comprising contacting one nare of the mammal with the device of claim 1 and delivering an effective dose of a therapeutic composition through the

Art Unit: 3761

device in a single inhaled breath of the mammal. It should be noted the method as recited is inherent in using the device of Barney.

16. **As to claim 16**, Barney teaches a method wherein the mammal is selected from the group consisting of a horse, a cow, a sheep, and a goat.

17. **As to claim 17**, Barney teaches a method wherein the mammal is a horse.

18. **As to claim 18**, Barney teaches a method wherein the therapeutic composition is administered in the form of a plume of aerosolized particles.

19. **As to claim 21**, Barney teaches a method wherein the therapeutic composition is administered in the form of dry powder (**See Col. 5, lines 34-35**).

20. **As to claim 22**, Barney teaches a device wherein the device lacks a rebreathing chamber.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barney in view of Foley et al (US 5988160).

23. **As to claims 4 and 5**, Crain teaches essentially all of the limitations except for wherein the device comprises a patient-actuated unidirectional inhalation valve.

However, Foley does teach a patient-actuated unidirectional inhalation valve so that air

Art Unit: 3761

is retained for a second inhalation and medicament is not wasted. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Crain to include a patient-actuated unidirectional inhalation valve so that air is retained for a second inhalation and medicament is not wasted.

24. Claims 19, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barney et al (US 6510818)

25. **As to claims 19 and 20**, Barney fails to specifically teach the limitations with respect to the particle size. However, such a limitation depends on the intended user along with the intended therapy and the type of medicament used (for particle size). Furthermore, Barney teaches (**Col. 6, lines 25-27**) that "one of skill will appreciate that practitioners may opt to alter dosages and/or formulations to fit a particular patient/animal needs." Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Barney to provide a particular particle size depending on the intended user along with the intended therapy and the type of medicament used.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Art Unit: 3761

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp
June 8, 2003



WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700